

✓
C3
Page 12, line 5, after "portion." insert - [When the needle 22 is bent into this U-shape, it is in a retracted position. The bent needle 22 is positioned inside the first lumen 24 of the catheter shaft 21 such that the catheter 21 acts as a restraint holding the bent needle 22 in its retracted position.--

[
IN THE CLAIMS

Please amend Claims 1, 7, 16, 32, 33, 36, 38-43, 46, 50 and 53-60, and cancel claim 35 as follows.

1. (twice amended) A method of treating a vessel having a vessel wall with an inner surface, the method comprising the steps of:

inserting a catheter having a vessel puncturing element disposed therein into a substantially tubular vessel;

positioning the puncturing element at the site in the vessel to be treated; [

C4
restraining said puncturing element such that it is maintained in a retracted position;

placing said puncturing element in a puncturing position in which said puncturing element is no longer restrained;

[removing a restraint that holds said puncturing element in a retracted position,]said puncturing element automatically moving in a direction substantially non-parallel with respect to a portion of said catheter that contains said puncturing element when said [restraint is removed] puncturing element is no longer being restrained.

267. (twice amended) A drug delivery device for treating a vessel having a vessel wall with an inner surface, the device comprising:

C5
an elongated catheter adapted to be inserted into the vessel;
said catheter comprising a puncturing element having a retracted position in which said puncturing element does not puncture said vessel wall, at least a portion of said puncturing element being housed in a portion of said catheter when said puncturing element is in said retracted position;

34 - 2 -

a restraint [holding] that contacts and holds said puncturing element in said retracted position;

C5 said puncturing element further having a puncturing position in which said puncturing element engages and punctures said vessel wall, said puncturing element being substantially non-parallel with respect to said portion of said catheter when said puncturing element is in said puncturing position;

said puncturing element automatically moving from said retracted position to said puncturing position when said restraint is [released] no longer being applied; and

delivery means coupled to said catheter [for] and delivering a drug [outside the inner surface of the vessel wall] through a puncture in the vessel wall. 31

C6 32 18. (once amended) The [invention] device defined in Claim 15 wherein said delivery means further comprises an injection device coupled to said inner shaft lumen for injecting fluid through said inner shaft lumen.

17 32. (once amended) A method of treating a vessel having a vessel wall with an inner surface, the method comprising the steps of:

inserting a catheter having a vessel puncturing element disposed therein into a substantially tubular vessel;

positioning the puncturing element at the site in the vessel to be treated;

C7 inflating an inflatable compartment adjacent said puncturing element to thereby [applying] apply an adjacent force adjacent said puncturing element to move said puncturing element in a direction substantially non-parallel with respect to a portion of said catheter that contains said puncturing element, said adjacent force moving said puncturing element from a retracted position to a puncturing position.

18 33. (once amended) The method of claim 17 32 further comprising the step of puncturing the vessel wall with the puncturing element [at the site to be treated with the puncturing element].

C8 ²⁵
36. (once amended) The method of claim [35] ¹⁷~~32~~ wherein said compartment inflates a predetermined amount to move said puncturing element a predetermined distance.

¹⁹
21 ~~38~~. (once amended) The method of claim [32] ~~34~~ wherein the step of applying said force moves said puncturing element a predetermined distance such that said drug is delivered to [the] an outer surface of the vessel wall.

¹⁹
22 ~~39~~. (once amended) The method of claim [32] ~~34~~ wherein the step of delivering the drug comprises delivery of the drug into tissue surrounding the vessel wall.

¹⁹
23 ~~40~~. (once amended) The method of claim [32] ~~34~~ wherein the step of delivering the drug comprises the step of delivering a drug in a time release module.

¹⁹
24 ~~41~~. (once amended) The method of claim [32] ~~34~~ wherein the delivery means includes said puncturing element having a drug delivery lumen and wherein the step of delivering the drug comprises delivering the drug through the drug delivery lumen.

C9 ¹⁹
38 ~~42~~. (once amended) A drug delivery device for treating a vessel having a vessel wall with an inner surface, the device comprising:

an elongated catheter adapted to be inserted into the vessel;
said catheter comprising a puncturing element having a retracted position in which said puncturing element does not puncture said vessel wall, at least a portion of said puncturing element being housed in a portion of said catheter when said puncturing element is in said retracted position;

said puncturing element further having a puncturing position in which said puncturing element engages and punctures said vessel wall, said puncturing element being substantially non-parallel with respect to said portion of said catheter when said puncturing element is in said puncturing position;

a movable surface comprising an inflatable compartment coupled to said catheter and adjacent said puncturing element to contact and move said puncturing element from said retracted position to

09 said puncturing position when said movable surface is moved toward said puncturing element.

39 ³⁸ ~~43~~. (once amended) The device of claim ~~42~~ wherein [said movable surface is part of an inflatable compartment, and] said movable surface is moved toward said puncturing element by inflating said inflatable compartment. 40

010 42 ~~46~~. (once amended) The device defined in claim ~~44~~ wherein [said catheter further comprises]:

said inflatable compartment comprises an inflatable balloon [coupled to said catheter]; and

an inflation lumen [extending] extends through said catheter for delivering inflation fluid to said balloon. 45

011 46 ~~50~~. (once amended) The [invention] device defined in claim ~~49~~ wherein said delivery means further comprises an injection device coupled to said inner shaft lumen for injecting fluid through said inner shaft lumen. 40

48 53. (once amended) The [method] device of claim ~~44~~ wherein said drug comprises an antiproliferative drug for the treatment of restenosis.

49 54. (once amended) The [method] device of claim ~~44~~ wherein said drug comprises an antiproliferative drug for the treatment of vascular disease. 40

50 55. (once amended) The [method] device of claim ~~44~~ wherein said drug comprises a specific inhibitor of cellular proliferation. 40

012 51 ~~56~~. (once amended) The [method] device of claim ~~44~~ wherein said drug comprises a specific inhibitor of thrombin. 40

52 ~~57~~. (once amended) The [method] device of claim ~~44~~ wherein said drug comprises a specific inhibitor of platelets. 40

53 ~~58~~. (once amended) The [method] device of claim ~~44~~ wherein said drug comprises a genetic material. 40

54 ~~59~~. (once amended) The [method] device of claim ~~44~~ wherein said drug comprises a genetic material that when incorporated into cells results in the expression of therapeutic materials. 40

55 ~~60~~. (once amended) The [method] device of claim ~~44~~ wherein said drug is incorporated into a time released matrix. 40